

**HIT-Enhanced Family History Documentation and Management in Primary Care:
A Cluster Randomized Trial of a Personalized Multi-Condition Risk Assessment in Primary
Care (Patient Risk Evaluation and Prevention or *PREP*)**

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Abstract

Purpose: We evaluated whether collection of risk factors to generate an electronic health record (EHR)-linked personalized health risk appraisal (HRA) for coronary heart disease (CHD), diabetes, breast and colorectal cancer (CRC) was associated with improved patient-provider communication, risk assessment, and breast cancer screening plans in the next year.

Scope: A pragmatic trial of adults with an upcoming visit to 11 primary care practices during 2013 - 2014 (n=3,703).

Methods: Pre-visit, intervention patients completed a risk factors/perceptions assessment and received a 1-page HRA; coded data were sent to the EHR. Post-visit, intervention patients again reported risk perception. Information was collected in the opposite order for the control arm; no data were sent to the EHR. Accuracy of self-perceived risk was assessed by comparing to calculated risk.

Results: The intervention was associated with improvement of patient-provider discussion of changes to improve health (78.5% vs. 74.1%; adjusted odds ratio 1.67; 99% confidence interval 1.07-2.60, p=0.003). A similar trend was observed toward discussion of risk (54.1% vs. 45.5%; 1.34; 0.97-1.85, p = 0.02). The intervention was associated with greater improvement in accuracy of self-perceived risk for diabetes (16.0% vs. 12.6%, p=0.006) and CRC (27.9% vs. 17.2%, p<0001), with a trend toward improvement for CHD and breast cancer. No changes in plans for breast cancer screening were observed. Systematic collection of patient self-reported risk factors and use of EHR-linked multi-condition HRAs in primary care have the potential to modestly improve communication and promote accuracy of self-perceived risk.

Key Words: risk assessment, primary care, prevention

Purpose

Advances in our understanding of an inherited component to several important chronic diseases have led to an increase in the importance of ascertaining and documenting family health history. Family health history reflects the complex interactions of genetics, environment, and behavioral characteristics that may be shared among family members. Recommendations for disease prevention and screening based on familial risk can be used to provide a personalized disease prevention plan that encourages a person to change behaviors to reduce the risk of disease, and participate in tailored screening and disease prevention.¹

The purpose of this project was to develop an electronic health record (EHR)-linked family health history assessment tool for four common diseases (coronary heart disease (CHD), type II diabetes (DM), breast and colorectal cancers) that: (1) collected patient self-reported data about family health history and lifestyle and behavioral risk factors; (2) calculated a personalized risk score for the conditions of interest based on the data reported by the patient and data existing in the EHR; and, (3) created a personalized risk report for patients, including tailored risk reduction information. We measured the reach and effectiveness of this EHR-linked family health history assessment tool by conducting a cluster randomized controlled trial (RCT) of adult primary care patients within the Brigham and Women's Primary Care Practice-Based Research Network.

Scope

Family health history and an individual's lifestyle are known contributors to risk of developing chronic diseases such as diabetes, heart disease, and cancer.^{1,2} Assessing this information in a systematic way may facilitate early identification of patients at greatest risk and promote informed decision making by patients and communication with their health care providers,³ yet barriers to implementing risk assessment in clinical practice include limited time and low provider confidence in risk assessment.^{4,5}

Effective use of health risk appraisals (HRAs) by patients in primary care settings may promote accurate risk assessment, motivate health promotion and behavior change, and facilitate population management in primary care.⁶ The Affordable Care Act (ACA) provides coverage for an annual wellness visit that includes the use of HRAs, yet little is known about the effectiveness of HRAs. While several validated, web-based risk calculators are available to the public (e.g., National Cancer Institute Breast Cancer Risk Assessment Tool, 2013 American College of Cardiology/American Heart Association Cardiovascular Risk Calculator), these tend to be disease-specific, and are not integrated with care. Few tools take a more holistic approach and present risk for several chronic diseases.⁷ The use of HRAs would arguably have greatest

value in the context of a primary care visit when a patient and clinician can discuss risk assessment and prevention.

Individualized risk assessment has become increasingly important as recommendations for screening and prevention move from a “one size fits all” approach to one that requires a more personalized approach. Recommendations for breast cancer screening provide several examples of this.⁸ The United States (US) Preventive Service Task Force recommends against routine screening for women in their 40’s and instead suggests that the decision to screen be based on a discussion of individual harms and benefits.⁹ The American Cancer Society recommends that women at high risk for breast cancer be screened with magnetic resonance imaging (MRI) in addition to mammography.¹⁰

The widespread deployment and “meaningful use” of electronic health records (EHRs) represents a high priority in the US.¹¹ This offers an opportunity to systematically integrate HRAs with EHRs with the ability to create customized decision support and recommendations for primary prevention and screening. This integration may overcome many of the prior barriers to the collection and synthesis of these data in primary care to promote informed decision-making.

We report on a pragmatic trial, Patient Risk Evaluation and Prevention (PREP), which systematically collected family health history and lifestyle risk factors from primary care patients and produced a personalized HRA for coronary heart disease (CHD), diabetes (DM), breast (for women) and colorectal cancer (CRC). The study goal was to examine whether the generation of such a report prior to an upcoming visit was associated with improved patient-provider communication about disease risk and changes that could be made to promote health, more accurate self-perceived risk assessment, and subsequent use of breast and CRC screening.

Methods

Study Design Overview

PREP was a pragmatic cluster randomized controlled trial (RCT) of adult primary care patients receiving care in the Brigham and Women’s Primary Care Practice Network. Pre-visit, intervention patients completed an assessment of their family history, lifestyle, and risk perception and then received a personalized HRA to discuss with their doctor (refer to Table 1 for study flow). Post-visit, intervention patients received an assessment that included just the risk perception questions to re-assess accuracy of self-perceived risk. We collected the same information from patients in the control clinics but in the reverse order so that no information was available for the visit. Post-visit, both arms received the outcome assessment described below. The protocol was reviewed and approved by the Institutional Review Board of Partners HealthCare and was registered at Clinicaltrials.gov (NCT01468675).

Setting and Eligibility

Patients were recruited from 11 primary care practices affiliated with Brigham and Women’s Hospital, including 2 hospital-based practices, 2 community health centers, and 7 community-based practices. Practices shared the use of a web-based, certified EHR. Eligible patients were adults between the ages of 30-75 years, who had an annual, new patient, or comprehensive visit scheduled, and spoke English or Spanish. We excluded patients who did not have a phone number or email address listed in the EHR.

Randomization and Recruitment

Randomization occurred at the level of the practice. Recruitment occurred between May 16, 2013 and November 4, 2014. Six weeks prior to their visit, patients received an informational letter that described the study and included a phone number to call if they wished to opt-out. Patients could participate either via a web-based or automated phone survey. Four weeks prior to their visit, English-speaking patients with an email address who did not opt-out were sent an email with the same content as the informational letter, and a link to complete a web-based version of the pre-visit survey, or to opt-out of the study (the web-based interface for the EHR was not available in Spanish). Two weeks before their visit, patients who only had a phone number listed in the EHR, were Spanish speaking, or did not complete the survey using the web version, were contacted using an automated phone script, in English or Spanish, that called up to 10 times over 2 weeks.

Data Collection Study Flow

For the *intervention* group, the pre-visit assessment included questions about family health history, lifestyle risk factors, and an assessment of self-perceived risk for developing each of the four conditions that they did not already have (Table 1).

Table 1. Study Flow

| Intervention | Control |
|--|--|
| Assessment 4-weeks Before Primary Care Provider (PCP) Visit | |
| <ul style="list-style-type: none">• Collection of risk factors and calculation of risk• Self-perceived risk | <ul style="list-style-type: none">• Self-perceived risk only |
| <ul style="list-style-type: none">• Health risk appraisal (HRA) with personalized recommendations sent to patient• Coded risk factor data sent to PCP | <ul style="list-style-type: none">• No risk HRA to patient• No coded risk factor data to PCP |
| PCP Visit | |
| Assessment 2 to 4 weeks After PCP Visit | |
| <ul style="list-style-type: none">• Self-perceived risk | <ul style="list-style-type: none">• Collection of risk factors and calculation of risk• Self-perceived risk |

| | |
|--|---|
| <ul style="list-style-type: none"> • Outcome Assessment | <ul style="list-style-type: none"> • Outcome assessment • HRA with personalized recommendations sent to patient • No coded risk factor data to PCP |
|--|---|

A 1-page HRA, described below, was mailed before their primary care provider (PCP) visit with a cover letter suggesting that they bring it to their upcoming visit to discuss with their provider. Coded data about family health history and lifestyle risk factors from intervention patients was sent to the patient’s EHR. These coded data elements were then available for providers to use in their documentation and by decision support algorithms to prompt the provider to consider particular activities (e.g., for smokers, decision support suggested counseling to quit). PCPs in the intervention clinics received an email the day of the patient’s visit informing them if a patient had provided data; an icon appeared on the provider schedule to indicate that a patient had self-reported risk factor data into the survey (Figure 1). Two - four weeks post-visit, intervention patients received a post-visit assessment that included questions about self-perceived risk.

Figure 1. Sample Provider Schedule Indicating Whether a Patient Had Reported Risk Factor Data

| Time | Status | Clinic | Patient Name | Sex/Age | Visit Type |
|----------------|--------|--------|---|---------|------------|
| TEST,VIEW,M.D. | | | | | |
| 10:00 - 10:20 | | H | BWHLMRHMTEST.SIX  | F 50 | NEW |
| 11:00 - 11:10 | | H | BWHLMRHMTEST.EIGHT  | F 51 | NEW |
| 11:00 - 11:10 | | H | BWHLMRHMTEST.EIGHTEEN  | F 81 | NEW |
| 12:00 - 12:10 | | H | BWHLMRHMTEST.NINETEEN  | F 66 | NEW |
| 13:00 - 13:10 | | H | BWHLMRHMTEST.FOUR  | F 41 | NEW |

For the *control* group, the pre-visit assessment only included questions on risk perception; following their PCP visit they received the longer assessment that included questions about family health history, lifestyle risk factors, and the questions to re-assess self-perceived risk. Patients in the control group who completed the post-visit assessment received the personalized HRA after their visit. None of the data provided by the control patients was sent to the patient’s EHR.

Health Risk Appraisal

Your Health Snapshot (YHS) is a self-administered HRA that is a briefer version of *Your Disease Risk* (www.yourdiseaserisk.wustl.edu), which uses validated algorithms to assign risk estimates based on relevant epidemiologic studies.^{12,13} The *YHS* report is appropriate for an 8th-grade literacy level and includes a risk chart displaying risk estimates for DM, CHD, CRC, and breast cancer as well as personalized tips on ways to reduce risk and statements reinforcing healthy behaviors. Patients who already had a personal history of any of the four conditions received a

tailored report that did not include a risk estimate for that condition. The PREP risk report (figure 2) was similar in appearance to that used in our prior work.⁷

Outcome Assessment

Patients in both arms received the same outcome assessment questions as part of the post-visit survey, including whether at their last visit with their PCP they had talked about: (1) their risk of developing diseases in the future, (2) changes that they could make to improve their health, and (3) speaking to a genetic counselor about whether they should consider getting genetic testing (examined only for individuals who were at high risk for any of the four conditions). Other outcomes included improvement in the accuracy of self-perceived risk for each of the conditions. This outcome was calculated for individuals with inaccurate risk perception before the visit, based on comparison of self-perceived risk to the calculated risk. For calculation of this outcome, we combined people with below average or average risk into a category of “normal” risk and compared this group to those categorized as “high” risk. Finally, women 40 years and above were asked whether they had discussed getting a mammogram in the next year with their PCP and if they planned to get a mammogram in the coming year. Using data from the EHR, we examined (1) whether women age 40 - 75 years received a mammogram in the 6 months following a PCP visit if it had been at least 12 months since their prior mammogram at the time of the visit, and (2) for men and women age 50 – 75 years whether they received a colonoscopy in the 6 months following the visit if it had been at least 10 years since their prior screening. All patients who completed an outcome assessment survey were entered into a monthly drawing to receive one of two \$100 gift cards.

Covariates

Other data about the participants were obtained from the EHR including, age, sex, race, education, ethnicity, marital status, insurance, body mass index (BMI), smoking status, prior personal history of CHD, diabetes, breast cancer or CRC, and comorbidity score.¹⁴

Statistical Analysis

We compared participants’ characteristics by group using two-sample t-tests, Wilcoxon tests, and chi-square tests. Because randomization was done at the clinic-level, we used logistic regression models with generalized estimating equations clustered on clinic. We adjusted for patient characteristics that were *a priori* felt to be important or that differed between the intervention and control groups. Statistical analyses were conducted using SAS version 9.2 (Cary, NC) with $p < 0.05$ as the criterion for statistical significance.

Sub-Analyses: Primary care providers’ ability to estimate their patients’ risk of disease

We completed a survey of PCPs whose patients participated in the PREP trial, to evaluate their ability to accurately estimate the disease risk of their patient panel for each of the conditions of interest by merging patient risk of each condition with a survey of the PCPs of participating

patients. We compared PCPs' estimates of the percentage of their patients at higher than average risk to the actual percentage based on the aggregation of their patients' calculated risks. The comparison of the proportion of providers who overestimated versus underestimated the percentage of their patients who were high risk was carried out using Bowker's test of symmetry. We also examined whether provider age and sex were associated with under, over, or correct estimation of population risk.

Figure 2. Sample Health Risk Appraisal

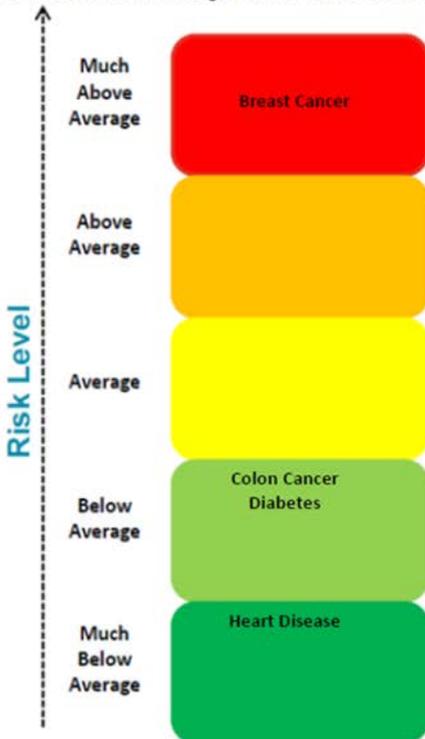
Your Health Snapshot

How is Your Health Risk Determined?

The graph below shows your estimated risk based on your answers to the questions you answered about your health behavior and family history. *If you have skipped some of the questions, these estimates may be less accurate.*

Your Risk

You have **Much Above Average** risk for **Breast Cancer**, **Below Average** risk for **Colon Cancer** and **Diabetes**, and **Much Below Average** risk for **Heart Disease**



Major things you can do to improve your health:

1. Achieve and maintain a healthy weight.
2. Eat a healthy diet low in red meat to reduce your risk of colorectal cancer.
3. Eat a healthy diet including fish two or more times per week to reduce your risk of heart disease

Keep up the good work. You're already doing these things to stay healthy:

1. You exercise regularly.
2. Maintain your healthy blood pressure.
3. Maintain your cholesterol level.
4. You eat whole grains (like whole wheat bread, brown rice, oatmeal or popcorn) most days.
5. You eat at least 3 servings of fruits and vegetables most days.
6. You eat nuts on most days.

My Watch List

In addition to your disease risk, you should also keep track of these factors that are important to your health and well-being.

Talk to Your Doctor

Because you have a family history of heart disease, be sure to talk to your doctor about your risk. Because you have a family history of cancer, be sure to talk to your doctor about your risk.

Weight

Losing some weight would improve your health and help you feel better overall. As little as 5 pounds can have real benefit. Talk to a doctor for some tips.

For more information about any of these conditions visit: <http://www.yourdiseaserisk.wustl.edu/>

Results

We attempted to contact 31,223 individuals (figure 3, consort diagram). The demographics of the sample are shown in Table 2. Overall 1.2% of individuals had a prior personal history of CRC, 8.2% of breast cancer, 8.6% of diabetes and 8.6% of CHD; these conditions were similar in both arms except that the prevalence of CHD was slightly higher among the controls. Among those without a personal history, 15.2% were at high risk for CRC, 19.7% for breast cancer, 17.4% for DM, and 8.4% for CHD.

Figure 3. CONSORT Diagram

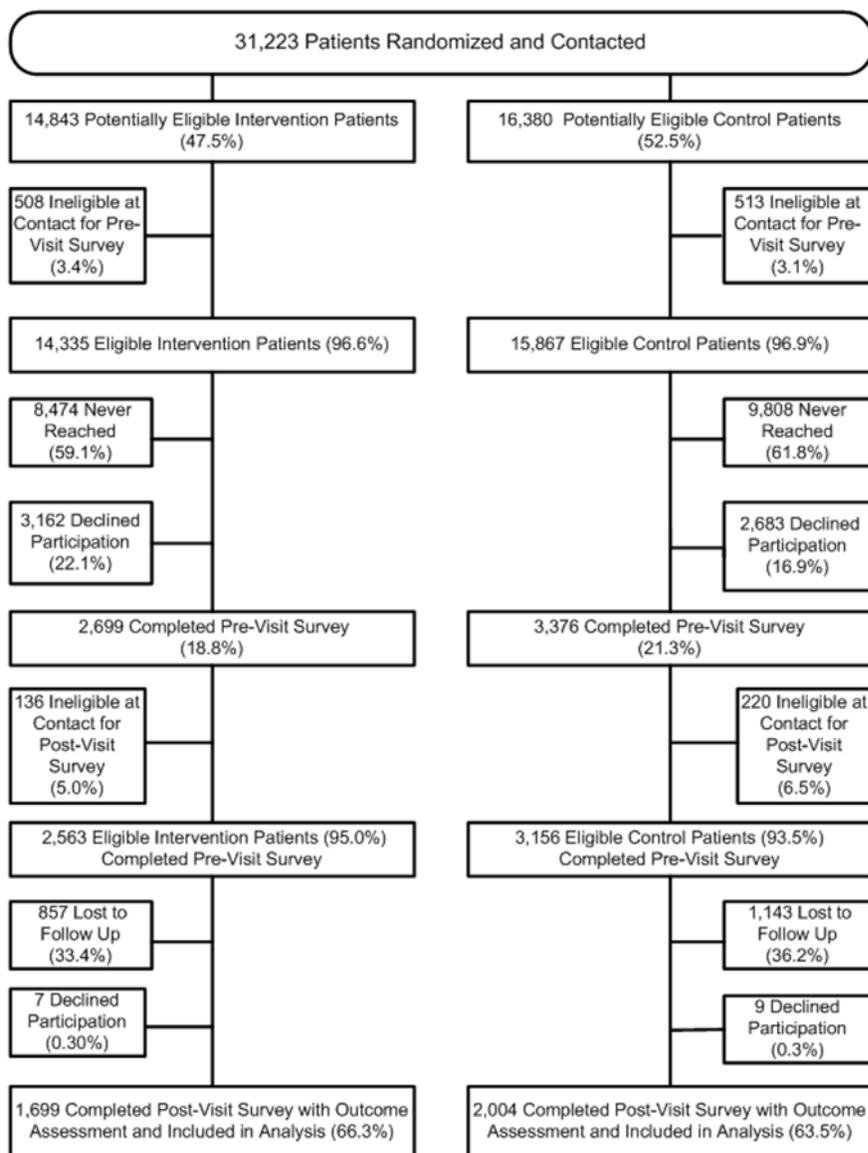


Table 2. Study Population

| | Intervention | Control | p-value |
|----------------------------|---------------------|----------------|----------------|
| | N (%) | N (%) | |
| N | 1699 | 2004 | |
| Median age, years | 55 | 56 | 0.18 |
| Sex: | | | |
| Female | 1338 (78.8) | 1415 (70.6) | <0.0001 |
| Race/ ethnicity: | | | |
| White | 1418 (83.5) | 1675 (83.6) | 0.78 |
| Black | 79 (4.7) | 82 (4.1) | |
| Latino | 91 (5.4) | 105 (5.2) | |
| Other/ unknown | 111 (6.5) | 142 (7.1) | |
| Married | 1101 (64.8) | 1456 (72.7) | <0.0001 |
| Insurance | | | |
| Private | 1231 (72.5) | 1435 (71.6) | 0.7995 |
| Medicare | 358 (21.1) | 430 (21.5) | |
| Medicaid/ Uninsured | 110 (6.4) | 139 (6.9) | |
| BMI Category | | | |
| Normal/underweight | 751 (44.3) | 725 (36.3) | <0.0001 |
| Overweight | 541 (31.9) | 729 (36.5) | |
| Obese | 404 (23.8) | 545 (27.3) | |
| Smoking status | | | |
| Current | 56 (3.3) | 90 (4.5) | <0.0001 |
| Former | 356 (21.0) | 557 (27.8) | |
| Never | 1287 (75.8) | 1357 (67.7) | |
| Prior personal history of: | | | |
| Diabetes | 145 (8.5) | 173 (8.6) | 0.9153 |
| Coronary Heart Disease | 129 (7.6) | 189 (9.4) | 0.0466 |
| Colorectal cancer | 21 (1.2) | 25 (1.3) | 0.9749 |
| Breast cancer (women only) | 107 (8.0) | 118 (8.3) | 0.7432 |
| Charlson score: | | | |
| 0 | 1514 (89.1) | 1828 (91.2) | 0.0285 |
| 1 | 118 (7.0) | 98 (4.9) | |
| 2+ | 67 (3.9) | 78 (3.9) | |
| High risk for developing: | | | |
| Diabetes | 232 (13.7) | 357 (17.8) | 0.0022 |

| | | | |
|--|-------------|-------------|---------|
| Coronary Heart Disease | 117 (6.9) | 167 (8.3) | 0.0258 |
| Colorectal cancer | 225 (13.2) | 332 (16.6) | 0.0179 |
| Breast cancer (women only) | 251 (18.8) | 246 (17.4) | 0.6322 |
| Pre visit self-perceived risk inaccurate | | | |
| CHD | 804 (51.2) | 777 (42.8) | <0.0001 |
| Diabetes | 1017 (65.4) | 1112 (60.7) | 0.0047 |
| CRC | 865 (51.3) | 928 (46.9) | 0.005. |
| Breast cancer (women only) | 675 (54.8) | 648 (50.0) | 0.0142 |

Patient-Provider Discussion

The intervention was associated with a trend towards patients reporting that they were more likely to have discussed their risk of developing a disease with their PCP (54.1% vs. 45.5%, adjusted odds ratio 1.34; 99% confidence interval 0.97-1.85, p=0.02) and was significantly associated with discussion of changes that they could make to improve their health (78.5% vs. 74.1%; 1.67, 1.07 – 2.60, p=0.003) (Table 3). Discussion of referral to a genetic counselor among those at high risk was similar.

Risk Perception

The intervention was associated with greater improvement in the accuracy of self-perceived risk following the PCP visit for diabetes (16.0% vs. 12.6%; 1.31 1.02-1.69, p=0.006) and CRC (27.9% vs. 17.2%; 1.83 1.25-2.68, p<0.001) with a similar trend for CHD (23.1% vs. 18.3%; 1.29 0.95-1.75, p=0.03) for breast cancer (21.0% vs. 15.9%; 1.39 0.97-2.00, p=0.02) (Table 3).

Table 3. Patient Report of Provider Discussion During their Visit and Improvement in Accuracy of Self-perceived Risk, and Plans for Breast Cancer Screening Among Women age 40 – 75 and Use of Breast and Colorectal Cancer Screening.

| | Intervention | Control | Adjusted Odds Ratio | 99% Confidence Interval | Adjusted p-value |
|---|---------------------|----------------|----------------------------|--------------------------------|-------------------------|
| | N (%) | N (%) | | | |
| During your last doctor visit did you talk with you PCP about: | | | | | |
| Your risk of developing diseases in the future, such as cancer, heart disease or diabetes? ¹ N Intervention 1673 N Control 1847 | 905 (54.1) | 841 (45.5) | 1.34 | (0.97 – 1.85) | .02 |
| Changes you can make to make to improve your health? ¹ N Intervention 1672 N Control 1852 | 1313 (78.5) | 1372 (74.1) | 1.67 | (1.07– 2.61) | .003 |
| Speaking to a genetic counselor to consider getting genetic test (among those at high risk for at least one of the four conditions with at least 1 family member) ² N Intervention 346 N Control 422 | 27 (7.8) | 32 (7.6) | 1.09 | 0.71-1.67 | .61 |
| Accurate Self-Perceived Risk Following Primary Care Visit (among those who did not have the condition and who were inaccurate prior to the visit): | | | | | |
| Coronary heart disease ² N Intervention 804 N Control 777 | 186 (23.1) | 142 (18.3) | 1.29 | 0.95-1.75 | .03 |
| Diabetes ² N Intervention 1017 N Control 1112 | 163 (16.0) | 140 (12.6) | 1.31 | 1.02-1.69 | .006 |
| Colorectal cancer ² N Intervention 865 N Control 928 | 241 (14.4) | 160 (8.1) | 1.94 | 1.43-2.63 | <.0001 |
| Breast cancer (women only) ³ N Intervention 675 | 142 (21.0) | 103 (15.9) | 1.39 | .097-2.00 | .02 |

| | | | | | |
|---|------------|------------|------|---------------|-------|
| N Control 648 | | | | | |
| Patient-reported discussion and plans for mammography (Women age 40 – 75, without breast cancer): | | | | | |
| During your last doctor visit did you talk with your PCP about whether you should get a mammogram this year (Women age 40 - 75)? *** N Intervention 963 N Control 1020 | 825 (85.7) | 905 (88.7) | 0.77 | (0.57 – 1.03) | .02 |
| Do you plan to get mammogram in the next 1 year? | | | | | |
| Women age 40 – 75 years ⁴ N Intervention 950 N Control 1008 | 883 (93.0) | 954 (94.6) | 0.78 | (0.51-1.18) | .1228 |
| Women age 40 – 49 years ⁴ N Intervention 228 N Control 244 | 205 (89.9) | 227 (93.0) | 0.65 | (0.31-1.41) | .1535 |
| Women age 50 – 75 years ⁴ N Intervention 722 N Control 764 | 678 (93.9) | 727 (95.2) | 0.80 | (0.47-1.38) | .2906 |
| 1 Adjusted for age, sex, marital status, BMI, smoking status, comorbidity score, being at high risk for developing colon cancer, breast cancer, diabetes or CHD, pre-visit survey modality. Clustered by site. 2 Adjusted for age, sex, marital status, BMI, smoking status, comorbidity score, pre-visit survey modality. Clustered by site. 3 Adjusted for age, marital status, BMI, smoking status, comorbid score, pre-visit survey modality. Clustered by site. 4 Adjusted for age, marital status, BMI, smoking status, comorbidity score, breast cancer risk, pre-visit survey modality. Clustered by site. | | | | | |

Plans for Cancer Screening

Among women, the intervention was not associated with plans to receive a mammogram in the coming year among all women age 40-75 years or among subgroups of women age 40-49 or 50-75 years. There was a trend towards greater discussion in the control arm of whether a woman should receive a mammogram (85.7% vs. 88.7%; 0.77, 0.57-1.03, p=0.02)

Sub-Analyses: Primary care providers' ability to estimate their patients' risk of disease

Significantly more providers (71.4%) overestimated their patient population's risk of CHD than underestimated risk (22.5%) (p-value = 0.001, with only 6.1% of providers estimating risk correctly). They were also more likely to overestimate (62.0%) than underestimate (6.1%) their patients' risk of diabetes (p-value = 0.008, with 32% of providers estimating correctly). In estimating cancer risks, providers were more likely to estimate correctly (43.9% for breast cancer and 36.5% for CRC), and there was no significant imbalance between over and underestimation.

Further research is needed to assess whether inaccurate provider estimation of patient risk at the panel or population level is related to screening and prevention recommendations at the individual patient level, particularly as providers weigh the competing risk of different common conditions.

Discussion

In this pragmatic trial, we found that systematic, pre-visit use of a multi-condition EHR-integrated, HRA in primary care has the potential to modestly improve patient-provider communication about risk and changes that can be made to improve health, and patient understanding of personal health risks, by linking patient-provided information with their health care team and providing personalized education, reminders, and health tips.^{6,14} We did not find evidence for changes in discussion of plans for mammography, perhaps because the information about breast cancer risk and recommendations were embedded with other disease risks and recommendations.

While there is a mixed literature on the effectiveness of HRAs in primary care,^{6,14,15} to our knowledge, our study is one of the few that examines an HRA integrated with an EHR. Our approach was also "holistic," addressing risk across several common conditions. We believe that this method is a strength for primary care practice, particularly since several factors (i.e., physical activity) convey risk for more than one condition, although this approach may dilute disease-specific messages and result in smaller changes in behavior. My Wellness Portal is a web-based personal health record (PHR) that supports the delivery of preventive health

services.¹⁶ This PHR includes a patient wellness plan, and an application that reminds patients about recommended preventive services, but is not integrated with decision support in an EHR. In a pilot trial of 400 adults, use of this PHR was associated with improved timely receipt of preventive services in aggregate (OR = 1.22; 95% CI, 1.12-1.32).¹⁶ A pragmatic trial of a free-standing, breast cancer-focused risk assessment tool in a primary care setting found improvements in discussion of breast cancer risk but also speaking with a genetic counselor.¹⁷ Several platforms assess risk based on family history alone.^{18,19} A pragmatic trial of Family Healthware, a web-based questionnaire that assesses familial risk for six diseases (ovarian cancer and stroke in addition to the four assessed in this study) was associated with improvements in risk perceptions, and modest increases in self-reported physical activity and fruit and vegetable intake, but a reduced likelihood of receiving cholesterol screening.²⁰

Our trial showed modest effects of this one-time assessment with written patient feedback and integration of patient provided data with decision support in the EHR. Several things could potentially improve the impact of HRAs. Ongoing access to a web-based portal, where patients could examine the effect of changes in lifestyle on risk could promote on going behavior change, particularly if linked to programs that can offer assistance.²¹ Several trends in primary care, including population management and shared records,^{22,23} offer the potential for greater integration of HRAs with services to promote health through programs to promote healthier lifestyles and personalized screening and health management. The ACA provides coverage for an annual wellness visit that promotes the development of a personalized prevention plan.²⁴ While our proactive outreach method only reached 20% of potentially eligible individuals, it is possible that implementation as part of a care plan would have higher participation rates as consent would not be required. Even small effects can lead to substantive health improvement at the population level. It is possible that individuals who participated in our study were more “health conscious.” Despite these limitations, this design more directly informs the effectiveness of this type of intervention in clinical settings. Our focus was on patient-reported outcomes. Longer follow-up is needed to assess the impact of this HRA on health behaviors, and use of services to improve health.

The widespread dissemination of EHRs that utilize a PHR offers the potential to broaden population-based risk assessment, and promote communication and risk perceptions that may lead to more personalized health prevention.

List of Publications and Products

Publications

Haas JS, Baer HJ, Eibensteiner K, Klinger EV, St. Hubert S, Getty G, Brawarsky P, Orav EJ, Onega TL, Tosteson AN, Bates DW, Colditz G. A Cluster Randomized Trial of a Personalized Multi-Condition Risk Assessment in Primary Care. American Journal of Preventive Medicine (revise and resubmit)

Brawarsky P, Baer HJ, Eibensteiner K, Klinger EV, St. Hubert S, Getty G, Brawarsky P, Orav EJ, Onega TL, Tosteson AN, Bates DW, Colditz G, Haas JS. Primary Care Providers' Ability to Estimate their Patients' Risk of Disease. Submitted for publication

Abstracts

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Invited Talks

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2015 Personalized Risk Assessment in Primary Care. International Cancer Screening Network, Rotterdam (Netherlands).

References

1. Yach D, Hawkes C, Gould CL, et al. The global burden of chronic diseases: overcoming impediments to prevention and control. *JAMA* 2004 Jun 2;291(21):2616-22. PMID: 15173153.
2. Yoon PW, Scheuner MT, Peterson-Oehlke KL, et al. Can family history be used as a tool for public health and preventive medicine? *Genet Med* 2002 Jul-Aug;4(4):304-10. PMID: 12172397.
3. Wang C, O'Neill SM, Rothrock N, et al. Comparison of risk perceptions and beliefs across common chronic diseases. *Prev Med* 2009 Feb;48(2):197-202. PMID: 19073208.
4. Sabatino SA, McCarthy EP, Phillips RS, et al. Breast cancer risk assessment and management in primary care: provider attitudes, practices, and barriers. *Cancer Detect Prev* 2007;31(5):375-83. PMID: 18037249.
5. Acheson LS, Wiesner GL, Zyzanski SJ, Goodwin MA, Stange KC. Family history-taking in community family practice: implications for genetic screening. *Genet Med* 2000 May-Jun;2(3):180-5. PMID: 11256663.
6. Baghelai C, Nelkin VS, Miller TR. *Health Risk Appraisals in Primary Care: Current Knowledge and Potential Applications to Improve Preventive Services and Chronic Care*. Rockville, Maryland: Agency for Healthcare Research & Quality. 2009.
7. Baer HJ, Schneider LI, Colditz GA, Dart H, Andry A, Williams DH, Orav EJ, Haas JS, Getty G, Whittemore E, Bates DW. Use of a Web-based Risk Appraisal Tool for Assessing Family History and Lifestyle Factors in Primary Care. *J Gen Intern Med* 2013 Jun;28(6):817-24. PMID: 23371384.
8. Onega T, Beaber EF, Sprague BL, Barlow WE, Haas JS, Tosteson AN, Schnall M D, Armstrong K, Schapira MM, Geller B, Weaver DL, Conant EF. Breast cancer screening in an era of personalized regimens: A conceptual model and National Cancer Institute initiative for risk-based and preference-based approaches at a population level. *Cancer* 2014 Oct 1;120(19):2955-64. PMID: 24830599.
9. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. *Ann Intern Med* 2009;151:727-37, W237-42. *Ann Intern Med* 2009 Nov 17;151(10):727-37. PMID: 19920273.
10. Saslow D, Boetes C, Burke W, Harms S, Leach MO, Lehman CD, Morris E, Pisano E, Schnall M, Sener S, Smith RA, Warner E, Yaffe M, Andrews KS, Russell CA. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. *CA Cancer J Clin* 2007 Mar-Apr;57(2):75-89. PMID: 17392385.
11. Blumenthal D, Tavenner M. The "meaningful use" regulation for electronic health records. *N Engl J Med* 2010 Aug 5;363(6):501-4. PMID: 20647183.
12. Colditz GA, Atwood KA, Emmons K, Monson RR, Willett WC, Trichopoulos D, Hunter DJ. Harvard report on cancer prevention volume 4: Harvard Cancer Risk Index. Risk Index Working Group, Harvard Center for Cancer Prevention. *Cancer Causes Control* 2000 Jul;11(6):477-88. PMID: 10880030.
13. Kim DJ, Rockhill B, Colditz GA. Validation of the Harvard Cancer Risk Index: a prediction tool for individual cancer risk. *J Clin Epidemiol* 2004 Apr;57(4):332-40. PMID: 15135833.
14. Kreuter MW, Strecher VJ. Changing inaccurate perceptions of health risk: results from a randomized trial. *Health Psychol* 1995 Jan;14(1):56-63. PMID: 7737074.

15. Wagner EH, Beery WL, Schoenbach VJ, Graham RM. An assessment of health hazard/health risk appraisal. *Am J Public Health* 1982 Apr;72(4):347-52. PMID: 7065313.
16. Nagykaldi ZJ, Voncken-Brewster V, Aspy CB, Mold JW. Novel computerized health risk appraisal may improve longitudinal health and wellness in primary care: a pilot study. *Appl Clin Inform* 2013 Feb 20;4(1):75-87. PMID: 23650489.
17. Kaplan CP, Livaudais-Toman J, Tice JA, Kerlikowske K, Gregorich SE, Perez-Stable EJ, Pasick RJ, Chen A, Quinn J, Karliner LS. A randomized, controlled trial to increase discussion of breast cancer in primary care. *Cancer Epidemiol Biomarkers Prev* 2014 Jul;23(7):1245-53. PMID: 24762560.
18. Wang C, Sen A, Ruffin MT, Nease DE, Jr., Gramling R, Acheson LS, O'Neill SM, Rubinstein WS. Family history assessment: impact on disease risk perceptions. *Am J Prev Med* 2012 Oct;43(4):392-8. PMID: 22992357.
19. Orlando LA, Wu RR, Beadles C, Himmel T, Buchanan AH, Powell KP, Hauser ER, Henrich VC, Ginsburg GS. Implementing family health history risk stratification in primary care: impact of guideline criteria on populations and resource demand. *Am J Med Genet C Semin Med Genet* 2014 Mar;166C(1):24-33. PMID: 24616329.
20. Ruffin MT 4th, Nease DE, Jr., Sen A, Pace WD, Wang C, Acheson LS, Rubinstein WS, O'Neill S, Gramling R. Effect of preventive messages tailored to family history on health behaviors: the Family Healthware Impact Trial. *Ann Fam Med* 2011 Jan-Feb;9(1):3-11. PMID: 21242555.
21. Haas JS, Linder JA, Park ER, Gonzalez I, Rigotti NA, Klinger EV, Kontos EZ, Zaslavsky AM, Brawarsky P, Marinacci LX, St Hubert S, Fleegler EW, Williams DR. Proactive tobacco cessation outreach to smokers of low socioeconomic status: a randomized clinical trial. *JAMA Intern Med* 2015 Feb;175(2):218-26. PMID: 25506771.
22. Chen EH, Bodenheimer T. Improving population health through team-based panel management: comment on "Electronic medical record reminders and panel management to improve primary care of elderly patients." *Arch Intern Med* 2011 Sep 26;171(17):1558-9. PMID: 21949164.
23. Halamka JD, Mandl KD, Tang PC. Early experiences with personal health records. *J Am Med Inform Assoc* 2008 Jan-Feb;15(1):1-7. PMID: 17947615.
24. Annual Wellness Visit (AWV), Including Personalized Prevention Plan Services (PPPS). MLN Matters No. MM7079. Washington, DC: Centers for Medicare & Medicaid Services; 2011.